

In re Patent Application of

**GEACH** 

Atty. Ref.: 613-96; Confirmation No. 3193

Appl. No. 10/537,047

TC/A.U. 1623

Filed: February 8, 2006

Examiner: Peselev

For: PREPARATION COMPRISING 1,3 AND/OR 1,6 BETA GLUCANS FOR THE TREATMENT OF INFECTIONS AND INFLAMMATIONS IN ANIMALS

\* \* \* \* \* \* \* \* \* \*

September 10, 2009

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## **RESPONSE**

This is responsive to the Official Action of March 10, 2009. Petition is hereby made for a three month extension of time for which our payment in the appropriate amount is attached.

Claims 16, 20-23, 31 and 32 are pending in the application. No amendments to the claims are offered at this time.

The Examiner appears to have accepted all the evidence applicant has submitted. This includes that the glucans in Rorstad are not water soluble and accepts that applicant's immersion treatment enables wound healing in fish. The particulate glucans in Rorstad are really very different from the soluble glucans applicant uses. In terms of efficacy, the soluble ones work and the insoluble ones either do not work or if they do, they work very slowly even when taken orally. Based upon the evidence of record it is counsel's understanding that the examiner regards the evidence to be relevant and correct.

Applicant understands the examiner's position to be as follows: Rorstad discloses "treatment" of fish by "aqueous exposure" using a non-water soluble glucan. Lehmann discloses

treatment of wounds in mammals such as fish!? using a water soluble glucan. It is therefore obvious to treat fish for wound healing by water immersion as Rorstad "treats" fish by aqueous exposure. This conclusion is incorrect.

The Examiner dismisses any suggestion that Lehmann is really concerned with mammals referring to the bizarre mention of fish in column 4. Lehmann discusses in some detail how the immune response is stimulated in a mammalian system. This is puzzling as the immune system of a fish is rather different to that of a mammal. The glucans are said to stimulate interleukins and TNF to support immune activities in mammals. There is no evidence that the soluble glucans of Lehmann stimulate the immune system in fish and obviously the immune systems of fish and mammals are very different. The Examples in Lehmann are based on mammalian cells (human cells in fact). There is no evidence in Lehmann of any immune stimulation in a fish.

The fish immune system is much more primitive than that of a mammal and their systems are not comparable. Lehmann offers no evidence at all that soluble glucans cause an immune response in fish.

The Official Action does not discuss whether a sufficient dose of glucan can be administered to a fish via water immersion. Applicant has made the point that Rorstad concerns prophylactic treatment of animals. He does not address the issue of treating inflammation or of wound healing but instead administers non-water soluble glucans to enhance the effect of a vaccine or to prevent disease.

Rorstad is exclusively concerned with prophylaxis and not with any treatment. The Examiner seems to accept that. At no point in fact does Rorstad suggest you can treat a disease in a fish with glucans. The present inventor is the first person to realize that clinical doses can be administered via water immersion using water soluble glucans.

Applicant agrees that the route of administration in Rorstad for his prophylactic treatment includes aqueous exposure. There is no definition of what this term actually means but water immersion appears to be a subset of aqueous exposure.

There is no teaching anywhere in Rorstad that sufficient active agent could be administered to cause wound healing in a fish by water immersion.

GEACH Appl. No. 10/537,047 September 10, 2009

3

The same goes for Lehmann. There is no suggestion in Lehmann even to use water immersion treatment and absolutely no suggestion that sufficient active agent can be administered to a fish via water immersion.

The Examiner argues that Rorstad discloses that non-soluble glucans can act prophylatically via aqueous exposure. That is not a disclosure that a different glucan, water soluble glucans, can act to treat wound healing or treat inflammation via water immersion. Where is the evidence in the prior art that wounds in fish are healed by immersing the fish in a water bath containing water soluble glucans? There is none.

The Examiner will be well aware of the recent swine flu epidemic. It has become routine to give patients at risk of catching swine flu the drug Tamiflu. This drug **prevents** patients getting swine flu. Once you have swine flu, Tamiflu does not actually treat the disease - it is not a cure at all. Prevention is different from cure.

Lehmann offers no hint that wound healing is possible by water immersion. For mammals of course, water immersion would be hopeless - it wouldn't work.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

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